IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
GREENVILLE DIVISION

KAMILAH YOUNG **PLAINTIFF**

V. **NO. 4:16-CV-00108-DMB-JMV**

BRISTOL-MYERS SQUIBB COMPANY;
ASTRAZENECA PLC;
ASTRAZENECA LP;
ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENECA AB **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

This products liability action is before the Court on the motions to dismiss of: (1) Bristol-Myers Squibb Company, and AstraZeneca Pharmaceuticals LP, Doc. #7; and (2) AstraZeneca AB, AstraZeneca LP, and AstraZeneca PLC, Doc. #20.

I
Procedural History

On April 27, 2016, Kamilah Young filed a complaint in the Circuit Court of Sunflower County, Mississippi, against Bristol-Myers Squibb Company, AstraZeneca PLC, Astrazeneca LP, AstraZeneca Pharmaceuticals LP, and AstraZeneca AB. Doc. #2. In her complaint, Young seeks to recover for injuries and damages caused by her ingestion of Farxiga, a drug researched, developed, sold, and/or marketed by the various defendants. *Id*.

On May 31, 2016, Bristol-Myers Squibb Company and AstraZeneca Pharmaceuticals LP ("Removing Defendants") removed the state court action to this Court. Doc. #1. Approximately one week later, on June 7, 2016, the Removing Defendants filed a motion to dismiss Young's complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Doc. #7. Young responded in opposition to the motion to dismiss on June 21, 2016, Doc. #17; and the Removing Defendants replied on June 29, 2016, Doc. #18.

On July 7, 2016, AstraZeneca AB, AstraZeneca LP, and AstraZeneca PLC ("Non-Removing Defendants"), filed a document "join[ing] and rely[ing] on" the Removing Defendants' motion to dismiss and reply.[1] Doc. #20. Young responded in opposition to this filing on July 21, 2016, Doc. #29; and the Non-Removing Defendants replied on August 1, 2016, Doc. #32.

II
Relevant Standard

> To survive a motion to dismiss [for failure to state a claim], a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal citations and punctuation omitted) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–58 (2007)). Under this standard, a court must "accept all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *New Orleans City v. Ambac Assurance Corp.*, 815 F.3d 196, 199–200 (5th Cir. 2016) (internal quotation marks omitted). However, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the

[1] The document is styled as a motion to dismiss but in substance only joins the Removing Defendants' motion, memorandum, and reply. *See generally United States v. Campos-Guel*, 245 F. App'x 743, 745 n.1 (10th Cir. 2007) ("[Courts] review the substance of ... arguments and not ... title[s]."); *Argueros v. Vargars*, No. 07-cv-904, 2008 WL 4179452, at *2 (W.D. Tex. Sep. 5, 2008) ("It is not the title of the motion that governs its consideration, but the substance."). To the extent the Non-Removing Defendants merely join the Removing Defendants' filings, Young's subsequent response, Doc. #29, amounts to an unauthorized sur-reply and the Non-Removing Defendants' subsequent reply is an unauthorized sur-sur-reply. Neither document therefore has been considered for the purpose of deciding the motion to dismiss. *See generally Figueroa v. Gates*, No. CV00-0415, 2001 WL 1182889, at *2 (C.D. Cal. Mar. 30, 2001) ("A conclusion that [a defendant] must separately file another motion to dismiss, where arguments articulated in the already filed [motion] are inclusive, would be illogical, and would require the kind of multiplication of effort it is best to avoid.").

elements of a cause of action will not do so." *Twombly*, 550 U.S. at 555.

III
Factual Allegations

A. Farxiga Development and Effects

At some point before 2014, Bristol-Myers Squibb and the AstraZeneca Defendants were involved in the research, development, and testing of Farxiga, a sodium-glucose cotransporter 2 ("SGLT-2") inhibitor designed to treat type-2 diabetes. Doc. #2 at ¶¶ 3–16, 23–24. SGLT-2 inhibitors inhibit renal glucose reabsorption with the goal of lowering blood glucose. *Id*. at ¶ 32. When taken, SGLT-2 inhibitors cause the kidneys to excrete, rather than metabolize, glucose. *Id*.

Because Farxiga, like other SGLT-2 inhibitors, prevents absorption of glucose, the "body's primary fuel," the bodies of patients on the medication break down fat instead. *Id*. at ¶ 33. When fat is broken down, acids called ketones are introduced into the body's blood stream, creating the potential for acidosis (excessive blood acidity). *Id*. at ¶ 33. Generally, to maintain blood-acid balance, the body excretes excess ketones through urination. *Id*. at ¶ 35. Accordingly, a patient suffering from ketoacidosis (excessive blood acidity caused by ketones) will generally report high blood-glucose levels and frequent urination. *Id*. at ¶ 34. However, "because Farxiga places the kidneys under duress by expelling significant amounts of glucose that has not been metabolized through the urinary tract, Farxiga users are often unable to obtain blood-acid balance without medical intervention." *Id*. at ¶ 35.

In the general population, ketoacidosis is rare for type-2 diabetics and "much more common" in type-1 diabetics. *Id*. at ¶ 38. This discrepancy is caused by the fact that type-1 diabetics, like Farxiga patients, are unable to metabolize glucose. *Id*.

B. Farxiga Approval and Marketing

On January 8, 2014, the United States Food and Drug Administration approved Farxiga for treatment of type-2 diabetes. *Id*. at ¶ 23. Following approval, the defendants each participated in the manufacturing, marketing, distribution, and sale of Farxiga. *Id*. at ¶ 28. Although Farxiga was indicated for only glycemic control in adult type-2 diabetics, the defendants marketed Farxiga for other purposes, including weight loss and blood pressure reduction. *Id*. at ¶ 37.

On May 15, 2015, the FDA issued a Public Health Advisory linking SGLT-2 inhibitors, including Farxiga, to diabetic ketoacidosis, a condition which can result in organ failure and death. *Id*. at ¶ 39. On December 4, 2015, the FDA, which had also received reports linking Farxiga to kidney injuries, including renal failure, required the defendants to change the Farxiga warning label to warn of ketoacidosis and urosepsis. *Id*. at ¶¶ 40–41. Before and after the FDA's advisories, the defendants "aggressively promote[d] Farxiga" and "did nothing to alert United States consumers, and health care professionals of the risks associated with Farxiga."[2] *Id*. at ¶¶ 42–43.

C. Young's Use of Farxiga

In or about May 2015, Young was prescribed Farxiga and began taking it as prescribed. Doc. #2 at ¶ 49. On or about May 31, 2015, Young fell ill with ketoacidosis. *Id*. at ¶ 54. On June 22, 2015, Young suffered renal failure and was hospitalized for approximately ten days. *Id*. at ¶¶ 54–55. This action followed.

[2] In July 2015, the defendants did, however, send warning letters to healthcare professionals in Canada and Australia "warning of Farxiga's ketoacidosis risk." Doc. #2 at ¶ 43.

IV
Analysis

In her complaint, Young asserts ten causes of action against the defendants based on: (1) strict liability (Count One); (2) manufacturing defect (Count Two); (3) design defect (Count Three); (4) failure to warn (Count Four); (5) negligence (Count Five); (6) breach of express warranty (Count Six); (7) breach of implied warranty (Count Seven); (8) negligent misrepresentation (Count Eight); (9) fraud (Count Nine); and (10) "violation of consumer protection laws" (Count Ten).

A. Common Law Claims (Counts One, Five, Seven, Eight, and Nine)

As an initial matter, the defendants argue in their motion that the Mississippi Products Liability Act subsumes Young's common law claims so as to require dismissal of the claims based on strict liability, negligence, breach of implied warranty, negligent misrepresentation, and fraud. Doc. #8 at 5–8.

The MPLA, which applies "in any action for damages caused by a product, including, but not limited to, any action based on a theory of strict liability in tort, [and] negligence or breach of implied warranty, except for commercial damage to the product itself" provides, in relevant part:

> The manufacturer, designer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer, designer or seller:
>
> (i) 1. The product was defective because it deviated in a material way from the manufacturer's or designer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or
>
> 2. The product was defective because it failed to contain adequate warnings or instructions, or
>
> 3. The product was designed in a defective manner, or
>
> 4. The product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied

in electing to use the product; and

(ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and

(iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

Miss. Code Ann § 11-1-63(a). Though the defendants argue that Young's claims for strict liability, negligence, breach of implied warranty, negligent misrepresentation, and fraud should be dismissed as subsumed by the MPLA, dismissal is not required merely because a claim falls under the MPLA's purview.

By its express terms, the MPLA applies to "any action for damages caused by a product." Miss. Code Ann. § 11-1-63(a). Although "[t]he statute clearly contemplates suits may be brought under the statute," the MPLA "does not preclude or bar an action, although it clearly creates what some may argue to be formidable obstacles for a plaintiff to overcome in order to prevail." *R.J. Reynolds Tobacco Co. v. King*, 921 So.2d 268, 273 (Miss. 2005). Accordingly, common law claims based on damages caused by a product are subsumed by the MPLA and must be analyzed under the statute. *Elliott v. El Paso Corp.*, 181 So.3d 263, 269 (Miss. 2015). Common law claims for damages caused by a product which seek to impose liability outside the MPLA's framework must be dismissed for failure to state a claim. *See id*. ("Plaintiffs' negligence and strict-liability-based products-liability claims against CPChem, Tri–State, and TGP must be analyzed under the MPLA. To the extent that Plaintiffs purport to make common-law negligence or strict-liability claims based on damages caused by odorant fade, we find that those claims fail as a matter of law.").

Practically, where a common law claim is subsumed by the MPLA and is brought alongside products liability claims based on the same theory of recovery, the proper course is to

dismiss the common law claim to the extent it is duplicative of the parallel products liability counts. *See, e.g., Cross v. Laboratories*, No. 1:05-cv-170, 2014 WL 11430933, at *3 (N.D. Miss. May 12, 2014) ("Plaintiffs' claims for negligence and warranty/misrepresentation are duplicative and subsumed by the MPLA and are dismissed. All claims under the MPLA shall remain viable at this juncture ...."); *Arnoult v. CL Med. SARL*, No. 1:14-cv-271, 2015 WL 5554301, at *3 (S.D. Miss. Sep. 21, 2015) ("Plaintiff's negligence claims against Uroplasty are governed by the MPLA, and Count 3 of the Complaint is subsumed by Counts 1 and 2.") (internal citation omitted). To the extent a subsumed common law count is asserted "as an independent tort claim outside the scope of the MPLA," the count must be dismissed for failure to state a claim." *Id.* ("The Court grants Uroplasty's motion to dismiss Count 3 insofar as it is asserted as an independent tort claim outside the scope of the MPLA.").

1. Strict Liability (Count One)

There is no dispute that a claim for strict liability based on damage caused by a product is subsumed by the MPLA. Miss. Code Ann § 11-1-63(a). Young's claim for strict liability includes allegations regarding: (1) defective design; (2) failure to warn; and (3) defective manufacture. Doc. #2 at ¶¶ 73–74, 81–82. In this regard, her strict liability claim in Count One is subsumed by Count Two (manufacturing defect), Count Three (design defect), and Count Four (failure to warn). Accordingly, Count One will be dismissed as duplicative of Young's product liability claims. To the extent Count One attempts to impose liability on other grounds, it will be dismissed for failure to state a claim.

2. Negligence (Count Five)

Claims for negligence are also subsumed by the MPLA. Miss. Code Ann § 11-1-63(a). Young's claim for negligence includes allegations regarding: (1) defective design; (2) failure to

warn; and (3) defective manufacture. Doc. #2 at ¶¶ 135, 138–40. In this regard, the claim is subsumed by Count Two (manufacturing defect), Count Three (design defect), and Count Four (failure to warn). Accordingly, to the extent Young's negligence claim in Count Five is subsumed by the product liability claims, Count Five will be dismissed as duplicative. To the extent Count Five attempts to impose liability on other grounds, it will be dismissed for failure to state a claim.

3. Breach of Implied Warranty (Count Seven)

Claims for breach of implied warranty are subsumed by the MPLA. Miss. Code Ann. § 11-1-63. Young's claim for breach of implied warranty in Count Seven alleges that the defendants breached the implied warranties of merchantability and fitness for particular purpose because Farxiga "was unduly dangerous and caused undue injuries ...." Doc. #2 at ¶ 174. In this regard, the claim is subsumed by Count Three (design defect). Accordingly, to the extent the claim is subsumed by the product liability claims, Count Seven will be dismissed as duplicative. To the extent Count Seven attempts to impose liability on other grounds, it will be dismissed for failure to state a claim.

4. Negligent Misrepresentation (Count Eight) and Fraud (Count Nine)

In a products liability action, negligent misrepresentation and fraud claims are subsumed by the MPLA unless the claims are "unrelated to the [product's] alleged defects." *Elliott*, 181 So.3d at 269. Young, citing this provision, contends that her "claims for Fraud and negligent misrepresentation are governed by the common law, not the MPLA." Doc. #17 at 18. However, both claims seek to recover for damages caused by the allegedly defective Farxiga and, therefore, fall within the MPLA's ambit. *See* Doc. #2 at ¶¶ 195, 214. In this regard, the claims are subsumed by Count Three (design defect) and Count Four (failure to warn) and must be

dismissed as duplicative. To the extent Counts Eight and Nine attempt to impose liability on other grounds, they will be dismissed for failure to state a claim.

5. Summary

Young's common law claims for strict liability, negligence, breach of implied warranty, negligent misrepresentation, and fraud are subsumed by the MPLA. To the extent these common law claims are duplicative of Young's product liability claims, the common law claims must be dismissed as duplicative. To the extent the common law claims are asserted as independent torts, they must be dismissed for failure to state a claim.

B. Design Defect (Count Three)

The defendants argue that Young's claim for defective design must fail because Young has failed to plead a feasible design alternative and because federal law preempts the design defect claims.

1. Preemption

"Under the doctrine of federal preemption, a federal law supersedes or supplants an inconsistent state law or regulation." *United States v. Zadeh*, 820 F.3d 746, 751 (5th Cir. 2016). Under the doctrine of conflict preemption, federal law will supersede or supplant state law "when compliance with both [the] state and federal law is impossible." *Id*. "Federal preemption is an affirmative defense that a defendant must plead and prove." *Fisher v. Halliburton*, 667 F.3d 602, 610 (5th Cir. 2012)." Accordingly, "[u]nless the complaint itself establishes the applicability of a federal-preemption defense – in which case the issue may properly be the subject of a Rule 12(b)(6) motion – a defendant should ordinarily raise preemption in a Rule 12(c) motion for judgment on the pleadings or a Rule 56 motion for summary judgment." *Id.* (internal footnotes omitted).

The defendants argue that federal law preempts Young's design defect claims because Young "alleges that Defendants should have designed Farxiga differently. ... [B]ut, critically, federal law prohibits Defendants from changing the design of Farxiga in a meaningful way without prior FDA approval." Doc. #8 at 21.

Today, pharmaceutical design defect claims are evaluated primarily against the framework set forth in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, under which a court begins by identifying a defendant's state and federal law duties and then asks whether it is possible to comply with both duties. 133 S.Ct. 2466, 2475–77 (2013). In *Bartlett*, the United States Supreme Court considered whether a design defect claim brought under New Hampshire state law against a generic drug manufacturer was preempted by federal law. The Supreme Court held that, under New Hampshire state law, a manufacturer must "ensure that the products they design, manufacture, and sell are not 'unreasonably dangerous.'" *Id*. at 2474. It further noted that under the risk-utility approach used in New Hampshire, a manufacturer could satisfy this duty "either by changing a drug's design or by changing its labeling." *Id*. Because federal law prevents a generic drug manufacturer from changing the drug's design or its label, the Supreme Court concluded that federal law preempted the plaintiff's state law claims. *Id.* at 2476–77.

a. State Law Duties

Under Mississippi law, a manufacturer has a duty to manufacture a product which is not defective and "unreasonably dangerous." Miss. Code Ann. § 11-1-63. "In most cases, the unreasonable danger presented by a product's design is the factor that makes the design defective." *Williams v. Bennett*, 921 So.2d 1269, 1274 (Miss. 2006). Unreasonable danger, in turn, is determined under the risk-utility approach utilized by most courts in the country. *See Smith v. Mack Trucks, Inc.*, 819 So.2d 1258, 1262–64 (Miss. 2002).

> Under the risk-utility theory, a plaintiff may recover for any injury as a result of the use of a dangerous product, provided that the utility of the product is outweighed by its danger. In balancing a product's utility against the risk of injury it creates, the factors to be considered are:
>
> (1) The usefulness and desirability of the product-its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product-the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Id. at 1262–63. Under this standard, "[i]f an alternative design could have been practically adopted at the time of sale, and if the omission of such an alternative design rendered the product not reasonably safe, than a design is defective." *Williams*, 921 So.2d at 1275.

b. Federal Law Duties

It is undisputed that, "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Bartlett*, 133 S.Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)). However, a brand name manufacturer, unlike a generic manufacturer, "may use the FDA's CBE regulation to unilaterally change its labeling without prior FDA approval." *Brazil v. Janssen*

Research and Dev. LLC, No. 4:15-cv-204, 2016 WL 4844442, at * 16 (N.D. Ga. Mar. 24, 2016).

c. Impossibility

The defendants argue that Young's design defect claims are preempted because there is a conflict between federal law requiring FDA approval to change Farxiga and the Mississippi law which "imposes a duty on a manufacturer, designer, or seller to adopt an alternative, safer design if the failure to do so makes a product unreasonably safe." Doc. #8 at 20–21. Young responds that "Federal law does not prohibit brand-name drug manufacturers from designing a reasonably safe drug before FDA approval, nor does it prohibit manufacturers from changing a drug's design post-approval to ensure it is reasonably safe." Doc. #17 at 7. Young is both right and wrong.

i. Post-Approval Changes

As clearly stated in *Bartlett*, "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" 133 S.Ct. at 2471. Accordingly, contrary to Young's assertion, federal law prohibits brand name drug manufacturers from altering a drug's design after receiving FDA approval. *Guidry v. Janssen Pharm., Inc.*, __ F.Supp.3d __, No. CV 15-4591, 2016 WL 4508342, at *14 (E.D. La. Aug. 29, 2016) ("[T]to the extent the plaintiff contends that the defendants should have adopted a new design for Invokana after it was approved by the FDA, her defective design claim is preempted.") (emphasis omitted).

ii. Pre-Approval Changes

Courts are, however, split on whether federal law acts as a bar on claims based on a contention that a brand name drug should have been designed properly *before* FDA approval. A

wide array of courts, focusing on a manufacturer's wide discretion to submit proposals to the FDA for approval, have held there is no conflict between a manufacturer's state law duty to produce a safe drug and its federal law duties to obtain approval.[3] However, the Sixth Circuit and a smattering of district courts have rejected this theory as "too attenuated" and/or equivalent to a "never-start selling rationale," which was rejected in *Bartlett*. *Yates v. Ortho-McNeal-Janssen Pharms., Inc.*, 808 F.3d 281, 299–300 (6th Cir. 2015).[4]

Specifically, the Sixth Circuit in *Yates* wrote:

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed ORTHO EVRA® differently, the FDA would have approved the alternate design. Next, we would have to assume that Yates would have selected this method of birth control. Further yet, we would have to suppose that this alternate design would not have caused Yates to suffer a stroke. This is several steps too far. Even if New York law requires defendants to produce and market a different design, the ultimate availability to Yates is contingent upon whether the FDA would approve the alternate design in the first place ....
>
> Yates's pre-approval claim fails for another reason. In *Bartlett*, the Supreme Court held that "[t]he [First Circuit] Court of Appeals' solution—that [the manufacturer] should simply have pulled [the drug] from the market in order to comply with both state and federal law—is no solution." 133 S.Ct. at 2470. This "stop-selling" rationale is "incompatible with ... preemption jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not

[3] *See Guidry*, 2016 WL 4508342, at *15 ("[T]he dispositive question presented here is simply: Can a drug manufacturer independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval? The answer is yes."); *Estate of Cassel v. Alza Corp.*, No. 12-cv-771, 2014 WL 856023, at *5–6 (W.D. Wisc. Mar. 5, 2014) ("No federal law prohibited defendants from submitting a different design (or at least, defendants have pointed to none). Similarly, defendants have offered no evidence that the FDA would have exercised its authority to prohibit defendants from creating and submitting such a design for approval.") (emphasis omitted); *Trahan v. Sandoz, Inc*., No. 3:13-CV-350-J-34MCR, 2015 WL 2365502, at *6 (M.D. Fla. Mar. 26, 2015) ("[I]n her Amended Complaint Trahan arguably states a claim that Sandoz breached its duty to design a reasonably safe product when it initially selected the defective glass, prior to FDA approval. Complying with its state law duty of care at that time was not 'impossible' in the absence of any federal law requiring Sandoz to utilize the allegedly defective glass container.") (emphasis omitted); *Sullivan v. Aventis, Inc.*, No. 14-cv-2939, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015) ("[C]ounsel has cited no federal law that restricts a brand-name drug manufacturer from designing a reasonably safe product *prior* to FDA approval.") (emphasis in original).

[4] *Utts v. Bristol-Myers Squibb Co.*, __ F.Supp.3d __, No. 16-cv-5668, 2016 WL 7429449, at *12 (Dec. 23, 2016) (pre-approval duty too attenuated); *Small v. Amgen, Inc.*, No. 2:12-cv-476, 2016 WL 4942078, at *2 (M.D. Fla. Jan. 25, 2016) ("[I]t is likely, even if Enbrel is capable of redesign, that any claim that Defendants should have changed Enbrel's design before seeking FDA approval would likewise be preempted.") (citing *Yates*); *Fleming v. Janssen Pharms., Inc.*, 186 F.Supp.3d 826, 833–34 (W.D. Tenn. 2016) (citing *Yates*).

> required to cease acting altogether in order to avoid liability." *Id*. at 2477. In contending that defendants' pre-approval duty would have resulted in a birth control patch with a different formulation, Yates essentially argues that defendants should never have sold the FDA-approved formulation of ORTHO EVRA® in the first place. We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale of the First Circuit.
>
> In sum, both Yates's pre-approval and post-approval design defect claims are preempted by federal law.

808 F.3d at 299–300. In rejecting these arguments, United States District Judge Martin L.C. Feldman of the Eastern District of Louisiana wrote:

> Indeed, every defective design claim requires consideration of hypothetical scenarios—what different steps could have been taken that may have prevented the plaintiff's injury. The only added assumption in the pharmaceutical context is that the FDA would have approved the safer, hypothetical drug. It is not too attenuated to assume that the FDA would approve a safer, alternative design of a drug that it has already approved. Nor does the Court share the Sixth Circuit's reservations about the so-called "never-start-selling" argument. Indeed, the raison d'être of products liability litigation is to penalize manufacturers who design unreasonably dangerous products in hopes that they never start selling them. State products liability law functions as a compliment to federal drug regulations to keep unreasonably dangerous drugs off the market.

Guidry, 2016 WL 4508342, at *15.

The Court finds Judge Feldman's analysis largely persuasive but would add two additional points.

First, the impossibility aspect of conflict preemption requires that a state law duty conflict with a federal law duty. If there is no state law duty, the state law cause of action must certainly fail but there can be no conflict so as to justify preemption. Put differently, the absence of a state law duty is fatal to a claim but not under the doctrine of conflict preemption. Here, the parties have not argued whether Mississippi law recognizes a pre-approval claim, and the Court does not reach the issue. Rather, for the purpose of addressing the defendants' preemption argument, it is sufficient to say that there is no conflict between Young's pre-approval theory and the

defendants' federal law duties.

Second, *Yates* misstates the "stop selling" rationale explained in *Bartlett*. In *Bartlett*, the Supreme Court rejected an argument that a generic manufacturer could avoid a conflict with federal and state law by "choosing not to make [the drug] at all." 133 S.Ct. at 2477 (internal alterations omitted). The Supreme Court held that such a doctrine was incompatible with preemption cases which "presume that an actor seeking to satisfy both his federal – and state law obligations is not required to cease acting altogether in order to avoid liability." *Id*. The pre-approval theory does not argue that a manufacturer should have stopped acting, just that it should have acted *differently*. Accordingly, the Court concludes that the stop selling doctrine does not preclude a pre-approval theory of recovery.[5]

2. Feasible Design Alternative

Under the MPLA:

> Plaintiffs alleging a defective design must show ... that at the time the product left the control of the manufacturer:

[5] Although not raised by Young in her response, the Court notes that even if Young could not proceed on a pre-approval theory, her design defect claim would still not be preempted. As explained above, Mississippi law recognizes a risk-utility approach for determining whether a product was defectively designed. Under this approach, a court considers the existence of suitable warnings or instructions. *Smith*, 819 So.2d at 1262–64. Because it is undisputed that a brand name manufacturer has the ability to unilaterally change its warning labels, in risk-utility jurisdictions, a plaintiff is not preempted from arguing that a product was defectively designed due to an insufficient warning label. *See Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 703 (3d Cir. 2016) ("[T]he Court has distinguished between brand-name drugs and their generic equivalents, determining that at least some state law tort claims may be brought against brand-name drug companies because such companies have the ability to make some unilateral changes to their labels without additional regulatory preapproval.") (emphasis omitted); *Utts v. Bristol–Myers Squibb Co.*, No. 16CV5668(DLC), 2016 WL 7429449, at *9 (S.D.N.Y. Dec. 23, 2016) ("If the claim addresses newly acquired information and addresses a design or labeling change that a manufacturer may unilaterally make without FDA approval, then there may be no preemption of the state law claim."); *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 3748771, at *10 (N.D. Ga. July 11, 2016) ("Any claim by Plaintiff that Defendants should change the formulation of Invokana is preempted by FDA regulations. Plaintiff, however, may argue that Defendants should be liable because a stronger warning would have changed Invokana's risk-utility profile to make it not unreasonable dangerous."); *Sullivan v. Aventis, Inc.*, No. 14-CV-2939-NSR, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015) ("Furthermore, even if redesign is not feasible, there is no federal law that prevents a manufacturer from complying with its state-law duty by strengthening a brand-name drug's warning label (pre- or post-approval).").

> (i) The manufacturer or seller knew, or in light of reasonably available knowledge or in the exercise of reasonable care should have known, about the danger that caused the damage for which recovery is sought; and
>
> (ii) The product failed to function as expected and there existed a feasible design alternative that would have to a reasonable probability prevented the harm. *A feasible design alternative is a design that would have to a reasonable probability prevented the harm without impairing the utility, usefulness, practicality or desirability of the product to users or consumers*.

3M Co. v. Johnson, 895 So.2d 151, 165 (Miss. 2005) (quoting Miss. Code Ann. § 11-1-63) (emphasis added). The defendants argue that Young's design defect claim must fail because "nowhere does Plaintiff identify with any specificity what alternative design is available." Doc. #8 at 17. The defendants further argue that Young's allegations do not offer an alternative design, but rather an alternative product, and that the proffered alterations would impair the utility, usefulness, practicality or desirability of Farxiga. *Id*. at 19.

a. Conclusory Allegations

The defendants, citing to *Austin v. Bayer Pharmaceuticals Corporation*,[6] argue that "[a] conclusory allegation that there was an alternative available without any facts about what that alternative design is does not state a claim under the MPLA." Doc. #8 at 17. Young, citing paragraphs 46, 109, and 110 of her complaint, responds that the "Complaint has adequately pled a feasible alternative design." Doc. #17 at 15–16.

The cited provisions of Young's complaint allege:

> 46. Consumers, including Plaintiff, who have used FARXIGA for treatment of diabetes, have several alternative safer products available for treatment. SGLT-2 inhibitors, including FARXIGA, are the only class of drugs which utilize the mechanism of expelling significant quantities of unmetabolized glucose through the kidneys to lower blood-glucose levels.
>
> * * *

[6] No. 5:13-cv-28, 2013 WL 5406589 (S.D. Miss. Sep. 25, 2013).

> 109. At the time FARXIGA left Defendants' control it was both technically and economically feasible to have an alternative design that would not cause renal failure, renal impairment, renal insufficiency and ketoacidosis, or an alternative design that would have substantially reduced the risk of these injuries.
>
> 110. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

Doc. #2 at 8–9, 22.

This Court agrees that Rule 8 requires more than a bare assertion that safer alternative products exist. *See Varney v. R.J. Reynolds Tobacco Co.*, 118 F.Supp.2d 63, 70 (D. Mass. 2000) ("Although the plaintiff states, in the sort of conclusory fashion that is insufficient, that safer alternative designs for cigarettes were available, there is not the slightest description of what those designs were or why they would have avoided causing harm to the plaintiff if adopted.") (internal citation omitted). However, Young's allegations go beyond a mere conclusory statement, although by a narrow thread. Young in essence alleges that the defendants could have designed their drug without using an SGLT-2 inhibitor. While, as discussed below, this allegation fails for another reason, it does not fail for lack of specificity.

b. Usefulness

Next, the defendants argue that any change from SGLT-2 would impair the utility, usefulness, practicality or desirability of the product to users or consumers. Beyond pointing out that SGLT-2 inhibitors have been approved by the FDA, the defendants offer no authority to support their argument. Under these circumstances, the argument does not defeat Young's defective design claim.

c. Different Product

The defendants further argue that, even if Young's allegations regarding non-SGLT-2 inhibitors are not conclusory, they refer to a different product, not an alternative design, and are

thus insufficient under the MPLA. Doc. #8 at 18; Doc. #18 at 4. Young responds that she merely "alleges a different formulation of the root product (prescription diabetes medication)." Doc. #17 at 16. As support for their respective positions, the parties argue over the meaning of three cases: *Elliott v. El Paso Corp.*, 181 So.3d 263 (Miss. 2015) (cited above); *Phillips 66 Co. v. Lofton*, 94 So.3d 1051 (Miss. 2012); and *Tersingi v. Wyeth*, 817 F.3d 364 (1st Cir. 2016).

In *Elliott*, the Mississippi Supreme Court held that a design defect claim brought against a natural gas odorant manufacturer failed "as a matter of law because no expert ... offered any alternative chemical design for the allegedly defective odorant. Instead, [the alleged] alternative design for odorant – requiring members of the affected public to buy gas detectors – is an additional warning system." 181 So.3d at 272. The court held that "[r]equiring an entirely different warning system, or requiring the affected public to use gas detectors in their homes, is not a feasible alternative design for natural-gas odorant." *Id*. at 273.

In *Lofton*, the Mississippi Supreme considered whether a plaintiff had introduced sufficient evidence of an alternative design for a viscosifier[7] which contained asbestos. The defendant argued that at the time the product left its control, "no other *asbestos* viscosifier was formulated ... so as to not generate breathable fibers during use ...." 94 So.3d at 1061 (emphasis in original). The *Lofton* court rejected the defendant's argument and held the plaintiff satisfied his burden by introducing evidence which "showed that alternative vi[s]cosifiers were available which did not contain asbestos ...." *Id*. at 1062. In reaching this conclusion, the court noted that evidence at trial revealed that "nonasbestos viscosifiers were available with similar characteristics and purposes ...." *Id*.

In *Tersingi*, a plaintiff sued the developer and marketer of Pondimin, a weight loss drug,

[7] A viscosifier is "used to increase the viscosity of (to thicken) drilling mud fluids" on oil and gas drilling rigs. *Lofton*, 94 So.3d at 1056.

which caused primary pulmonary hypertension. 817 F.3d at 365. The plaintiff attempted to argue that the defendant could be held liable "because, at the time Pondimin was marketed, there were other, safer methods of weight loss available." *Id*. at 368. The First Circuit rejected the plaintiff's argument as inconsistent with "the reasonable alternative design inquiry, which requires the plaintiff to show that the product in question could have been more safely designed, not that a different product was somehow safer." *Id*.

Neither party has cited, and this Court has been unable to find, a Mississippi case addressing, as *Tersingi* did, the alternative design/different product distinction in the context of pharmaceuticals. However, courts throughout the country have held that a party may not show a reasonable alternative design by pointing to the availability of a different drug available for the same purpose. *See, e.g., Brown v. Johnson & Johnson*, 64 F.Supp.3d 717, 722 (E.D. Pa. 2014) ("Defendants correctly argue that acetaminophen is not an alternative to ibuprofen but an entirely different product."); *Salvio v. Amgen Inc.*, No. 2;11-cv-553, 2012 WL 517446, at *7 (W.D. Pa. Feb. 15, 2012) ("Plaintiff has failed to allege any alternative ways in which Enbrel could have been designed. Instead, he merely lists completely different drugs that Decedent could have taken."); *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 770–71 (Tex. Ct. App. 2009) ("Brockert does not explain how Prempro could have been modified or improved; she instead argues that progestin should not have been added to estrogen. In essence, Brockert argues that the product Prempro should have been a different product: its predecessor Premarin."); *Massa v. Genentech Inc.*, No. H-11-70, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012) ("Massa's argument that Raptiva could have been formulated with a number of alternative underlying compounds is not an argument that Raptiva should have been safer; it is an argument that Raptiva should have been a different product.") (emphasis and internal quotation marks omitted).

The question of whether an "alternative design is in fact a different product is generally a question of fact for the jury." *Keffer v. Wyeth*, 791 F.Supp.2d 539, 549 (S.D.W.V. 2011); *Torkie-Tork v. Wyeth*, 739 F.Supp.2d 895, 900 (E.D. Va. 2010). However, the issue may be decided on a motion to dismiss where the allegations fail as a matter of law. *Massa*, 2012 WL 956192, at *6 (granting motion to dismiss based on conclusion that alternative design was a different product).

Young attempts to satisfy her alternative design burden by pointing not just to a different drug but to a different class of drugs (non SGLT-2 inhibitors) which do not "utilize the mechanism of expelling significant quantities of unmetabolized glucose through the kidneys to lower blood-glucose levels." Doc. #2 at ¶ 46. Wherever Mississippi draws the line between an alternative design and a different product, the Court has no trouble concluding that Young's allegations, which point to drugs which by their very nature perform a different function, fall well on the latter side of such a line. Accordingly, the design defect claim must fail.

3. Summary

The Court concludes that Young's design defect claim is not preempted by federal law. However, as explained above, the claim must be dismissed for failure to plead a feasible alternative design.

C. Failure to Warn (Count Four)

"A manufacturer is liable under a failure-to-warn theory if the product 'failed to contain adequate warnings,' the inadequate warnings 'rendered the product unreasonably dangerous to the user or consumer,' and the inadequate warning 'proximately caused the damages for which recovery is sought.'" *Union Carbide Corp. v. Nix, Jr.*, 142 So.3d 374, 385 (Miss. 2014) (quoting Miss. Code Ann. § 11-1-63(a)(i)–(iii)). However, a defendant will not be liable for failure to

warn unless the plaintiff proves "that at the time the product left the control of the [defendant, the defendant] knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition." Miss. Code Ann § 11-1-63(c)(i).

In their motion to dismiss, the defendants argue that the failure to warn claim must be dismissed because: (1) the defendants provided an adequate warning for Farxiga's risk of renal impairment; (2) the claim seeks to recover for health risks Young did not suffer; and (3) the defendants were not required to warn of the risks of ketoacidosis.

1. Renal Impairment Warning

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

Miss. Code Ann. § 11-1-63(c)(ii). "The issue of a warning's adequacy is factual and usually will be resolved by the trier of the fact." *Union Carbide*, 142 So.3d at 389 (internal quotation marks omitted).

The defendants argue that Young's claims related to renal damage must fail because the prescribing information for the drug warned prescribing physicians about impairment of renal function. Doc. #8 at 25.

Of relevance here, the first page of the prescribing information, under a section titled "**WARNINGS AND PRECAUTIONS**," states "*Impairment in renal function:* Monitor renal

function during therapy. (5.2)."[8] Section 5.2, in turn, reads:

> **5 WARNINGS AND PRECAUTIONS**
>
> * * *
>
> **5.2 Impairment in Renal Function**
>
> FARXIGA increases serum creatinine and decreases eGFR. Elderly patients and patients with impaired renal function may be more susceptible to these changes. Adverse reactions related to renal function can occur after initiating FARXIGA [see Adverse Reactions (6.1)]. Renal function should be evaluated prior to initiation of FARXIGA and monitored periodically thereafter.

The referenced section 6.1 reads:

> **6 ADVERSE REACTIONS**
> The following important adverse reactions are described below and elsewhere in the labeling:
>
> * * *
>
> • Impairment in Renal Function [see *Warnings and Precautions* (5.2)]
>
> * * *
>
> **Impairment of Renal Function**
>
> Use of FARXIGA was associated with increases in serum creatinine and decreases in eGFR (see Table 3). In patients with normal or mildly impaired renal function at baseline, serum creatinine and eGFR returned to baseline values at Week 24. Renal-related adverse reactions, including renal failure and blood creatinine increase, were more frequent in patients treated with FARXIGA (see Table 4). Elderly patients and patients with impaired renal function were more susceptible to these adverse reactions (see Table 4). Sustained decreases in eGFR were seen in patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m^2).

Under the "learned intermediary doctrine," "pharmaceutical companies are required to

[8] A pharmaceutical's prescribing information is a public record. *In re Ariad Pharms., Inc.*, 98 F.Supp.3d 147, 174 (D. Mass. 2015), *reversed on other grounds sub nom., In re Ariad Pharm., Inc. Sec. Litig.*, 842 F.3d 744 (1st Cir. 2016). "[I]t is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record." *Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007). The prescribing information for Farxiga is available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202293s003lbl.pdf.

warn only the prescribing physician of dangers inherent in its products because the prescribing physician acts as a 'learned intermediary' between the manufacturer and the consumer." *Moore ex rel. Moore v. Mem'l Hosp. of Gulfport*, 825 So.2d 658, 662 n.6 (Miss. 2002). Accordingly, if the prescribing information provided an adequate warning to a physician, then Young's claim must fail. *See Deese v. Immunex Corp.*, 2012 WL 463722, at *4 (S.D. Miss. Feb. 13, 2012) ("[U]nder Mississippi's learned intermediary doctrine, the relevant question is whether Defendants adequately warned Deese's prescribing physician of the adverse effects of Enbrel, not whether Deese himself was adequately warned.").

In arguing that the warning is inadequate, Young contends that the prescribing information does not "specifically warn[] of renal failure, but instead uses language designed to downplay the association of renal failure and Farxiga." Doc. #17 at 12–13 (emphasis omitted). Young further argues that the warning does not "account for the numerous other forms of communication about the risks and benefits of Farxiga which were provided to Plaintiff and her physician, and which may have implications on the adequacy of the warning." *Id*. at 12 (citing to negligent misrepresentation claim).

Under the MPLA, to be adequate, a warning for a prescription drug must be one that "a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, ... taking into account the characteristics of, ... and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product." Miss. Code Ann. § 11-1-63(c)(ii). Young has alleged that "[t]he warnings that were given ... failed to properly warn physicians of the risks associated with FARXIGA." Doc. #2 at ¶ 124. Neither the prescription information nor the complaint itself offers any indication of the

adequacy of the warning in light of the ordinary knowledge common to a physician. Accordingly, nothing in the prescription information or the complaint itself contradicts this allegation. Therefore, the defendants' argument regarding the adequacy of the warning must be rejected.

2. Additional Health Problems

The defendants argue that "to the extent the failure-to-warn claim is premised on alleged risks that Plaintiff did not suffer – renal infection, urosepsis, or heart attack – the Complaint fails to state a claim." Doc. #8 at 26 (internal citation omitted). Young responds that she only alleges two injuries in her complaint – ketoacidosis and renal failure. Doc. #17 at 11–12. To the extent the defendants seek to dismiss claims not pled by Young, the motion will be denied.

3. Ketoacidosis

The defendants argue that "the failure to warn claim relating to ketoacidosis should be dismissed because the Complaint fails to allege any facts that would create a duty to warn about that adverse event." Doc. #8 at 27. Specifically, the defendants contend that Young "does not allege sufficient facts to support a reasonable inference that Defendants knew about [the] risk *at the time* they distributed the drugs." *Id.* Young responds that "the Complaint has adequately alleged a plausible duty to warn of ketoacidosis under two theories:" (1) "the Complaint alleges Defendants 'failed to investigate, research [and] study' the risks of Farxiga;" and (2) the May 15, 2015, FDA public health advisory creates a "reasonable inference ... that at the time Plaintiff was prescribed, purchased, and first used Farxiga, Defendants[] knew or should have known about the risk of ketoacidosis." Doc. #17 at 11–12. The defendants reply that Young "alleges no facts showing that Defendants knew or should have known about the risk of DKA at the time Plaintiff was prescribed Farxiga. She does not even allege the date she was prescribed Farxiga, and fails

to allege that Defendants had any knowledge of the FDA's Safety Communication before it was issued on May 15, 2015." Doc. #18 at 2. The Court agrees that both of Young's theories of knowledge must fail.

As explained above, a defendant will not be liable for a failure to warn unless the plaintiff proves "that at the time the product left the control of the [defendant, the defendant] knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition." Miss. Code Ann § 11-1-63(c)(i). Young has not alleged that the defendants had knowledge of the FDA communication before the Farxiga Young ingested left their control. Furthermore, while Young argues that the defendants should have been aware of the ketoacidosis risk through investigation, research, and study, she has not alleged that the facts regarding ketoacidosis risk were reasonably available to the defendants through such investigation. Under these circumstances, the defendants' motion to dismiss will be granted to the extent the failure to warn claim is based on injuries caused by ketoacidosis.

4. Summary

The defendants' motion to dismiss: (1) will be denied to the extent it seeks dismissal of the failure to warn claim based on Young's renal failure, (2) will be denied as moot to the extent it seeks dismissal of claims not pled by Young, and (3) will be granted to the extent it seeks dismissal of the failure to warn claim based on Young's ketoacidosis.

D. Manufacturing Defect (Count Two)

To sustain a claim for a manufacturing defect, a plaintiff must show that "[t]he product was defective because it deviated in a material way from the manufacturer's or designer's specifications or from otherwise identical units manufactured to the same manufacturing

specifications." Miss. Code Ann. § 11-1-63(a)(1).

In her complaint, Young alleges "FARXIGA was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or that it deviated from the product specifications and/or applicable requirements, and posed a risk of serious injury and death." Doc. #2 at ¶ 91. In their motion to dismiss, the defendants argue that the manufacturing defect claim must fail because "[t]he Complaint makes no factual allegations *how* the Farxiga ingested by Plaintiff 'was manufactured in a way which deviated from the design specifications." Doc. #8 at 15. Young responds that, "[a]t this early stage, Plaintiff is not privy to specific information which details the ways in which Defendants manufacturing process deviated from specifications, because Defendants are in sole possession of such information." Doc. #17 at 17.

While it has been observed that "[c]ourts typically allow the pleader an extra modicum of leeway where the information supporting the complainant's case is under the exclusive control of the defendant," *United States v. Baxter Intern.*, 345 F.3d 866, 882 (11th Cir. 2003), Young cites no authority for the proposition that exclusive control of information totally excuses a plaintiff from pleading more than a bare recitation of the elements of a cause of action, as she has done here. Additionally, Young does not argue how knowledge of the allegedly defective pills she took, which were ostensibly in her control, fall within the exclusive knowledge of the defendants. Rather, and as pointed out by the defendants, courts routinely dismiss manufacturing defect claims for failure to comply with Rule 8's pleading standards. *See, e.g.*, *Deese v. Immunex Corp.*, No. 3:11-cv-373 2012 WL 463722, at *3 (S.D. Miss. Feb. 13, 2012) (dismissing manufacturing defect claim because plaintiff "offer[ed] no indication of the particular grounds supporting a manufacturing ... defect claim in an amended complaint"); *Adams v. Energizer*

Holdings, Inc., No. 3:12-cv-797, 2013 WL 1791373, at *3 (S.D. Miss. Apr. 19, 2013) ("Plaintiffs purport to claim a manufacturing defect but do not allege how the subject product(s) deviated from the manufacturers' specifications or other units."). Because Young has wholly failed to plead how the Farxiga she took departed from the medication's design specifications, her manufacturing defect claim must be dismissed.

E. Breach of Express Warranty (Count Six)

To support liability for breach of express warranty under the MPLA, a plaintiff must show that "[t]he product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product." Miss. Code Ann. § 11-1-63(a)(i)(4). An express warranty "is any affirmation of fact or promise which concerns the product and becomes part of the basis for the purchase of such a product." *Forbes v. Gen. Motors Corp.*, 935 So.2d 869, 876 (Miss. 2006).

In her complaint, Young alleges:

> Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written material disseminated by Defendants or their authorized agents or sales represents, that FARXIGA:
>
> a. was safe and fit for its intended purposes;
> b. was of merchantable quality;
> c. did not produce any dangerous and life threatening side effects, and
> d. had been adequately tested and found to be safe and effective for the treatment of diabetes.

Doc. #2 at ¶ 148. Young further alleges that she relied on these representations, and that Farxiga did not conform to the representations. *Id*. at ¶¶ 153, 156.

The defendants argue that the claim must fail because Young "offers no specificity about what specific statements either Defendant allegedly made about Farxiga that the plaintiff or her prescribing physician relied upon." Doc. #8 at 28–29.

As an initial matter, a claim for breach of express warranty "clearly is not" subject to Rule 9(b)'s heightened pleading requirements. *Schouest v. Medtronic, Inc.*, 13 F.Supp.3d 692, 709 n.9 (S.D. Tex. 2014). Thus, there is no need for a plaintiff to allege a specific time and place of a warranty. Indeed, under Rule 8's more relaxed pleading standards, courts have found similar allegations to be sufficient to state a claim for express warranty. *See, e.g.*, *Huntley v. CL Med. SARL*, No. 2:14-cv-105, 2015 WL 5521796, at *3–4 (S.D. Miss. Sep. 16, 2015) (denying motion to dismiss where "Plaintiff specifically noted CLMI's website, which allegedly claims that the 'I–STOP provides patients with a fast, effective and minimally invasive procedure,' and that it has 'superior characteristics in the clinical setting.'"); *Rosenstern v. Allegran, Inc.*, 987 F.Supp.2d 795, 805 (N.D. Ill. 2013) (denying motion to dismiss based on similar allegations).[9] In view of this authority and the lenient pleading standards of Rule 8, the Court concludes that, while a close call, Young has alleged the express warranties with enough specificity to survive the defendants' motion.[10]

F. Fraud Based Claims (Counts Eight, Nine, and Ten)

Finally, the defendants argue that, even if not subsumed by the MPLA, Young's claims which sound in fraud must be dismissed for failure to satisfy the pleading requirements of Rule 9(b). Under Rule 9(b) of the Federal Rules of Civil Procedure, "[i]n alleging fraud or mistake, a

[9] The defendants point to *Deese*, in which a district judge held insufficient an allegation that "Defendants ... through their advertising, marketing and product labeling, expressly warranted that Enbrel was reasonably safe for use as a prescription treatment for persons suffering from rheumatoid arthritis such as Deese." 2012 WL 463722, at *6. The *Deese* court held that such an allegation "fails to identify ... any express warranty or express factual representation made by Defendants that they allegedly breached." *Id.* The Court finds the allegations in this case to be more specific than those in *Deese*.

[10] In reaching this conclusion, the Court notes that, while not raised by the defendants, Young's breach of express warranty claim must fail to the extent it is based on alleged omissions in Farxiga's prescribing information. An omission is neither an affirmation of fact nor a promise. *See generally Sidco Prods. Mktg. v. Gulf Oil Corp.*, 858 F.2d 1095, 1099 (5th Cir. 1988) ("Omissions, however, are not affirmative representations of any sort and thus cannot support a warranty claim, because express warranties must be explicit.") (applying Texas law).

party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." "Rule 9(b) applies by its plain language to all averments of fraud, whether they are part of a claim of fraud or not." *Lone Star Ladies Inv. Club v. Scholtzsky's Inc.*, 238 F.3d 363, 368 (5th Cir. 2001). The defendants argue, and Young does not dispute, that Rule 9(b) applies to Young's claims for fraud, negligent misrepresentation, and violations of Mississippi's Consumer Protection Act, all of which rely on allegations of fraudulent or deceptive behavior.[11] Doc. #8 at 31.

"What constitutes 'particularity' will necessarily differ with the facts of each case. At a minimum, Rule 9(b) requires allegations of the particulars of time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby. Put simply, Rule 9(b) requires 'the who, what, when, where, and how' to be laid out." *Benchmark Elecs., Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 724 (5th Cir. 2003) (internal punctuation and citations omitted). With regard to the how, "[t]he Fifth Circuit ... and other district courts within [the circuit] have either held or strongly suggested that Rule 9(b)'s particularity requirement extends to allegations of actual reliance." *In re BP P.L.C. Sec. Litig.*, No. 4:12–cv–1256, 2013 WL 6383968, at *39 (S.D. Tex. Dec. 5, 2013) (collecting cases). "[A]t a minimum, Rule 9(b) requires Plaintiffs to specify with particularity what actions [they took] or forewent in reliance upon Defendants' alleged misrepresentations." *Id.* at *41 (internal punctuation and emphasis omitted).

[11] *See generally Benchmark Elecs.*, 343 F.3d at 723 ("Although Rule 9(b) by its terms does not apply to negligent misrepresentation claims, this court has applied the heightened pleading requirements when the parties have not urged a separate focus on the negligent misrepresentation claims. That is the case here, as Benchmark's fraud and negligent misrepresentation claims are based on the same set of alleged facts.") (internal citations omitted); *Frith v. Guardian Life Ins. Co. of Am.*, 9 F.Supp.2d 734, 742 (S.D. Tex. 1998) (Rule 9(b) applied to allegations of fraud brought under Texas Consumer Protection Act).

Here, Young alleges that the defendants made a number of misrepresentations and omissions related to Farxiga's safety and that "Defendants[ʻ] misrepresentations were made through various methods, including but not limited to, FARXIGA's published labeling and medication guide, medical literature, promotional materials directed at consumers, promotional materials directed at health care professionals, and documentation submitted in support of FARXIGA's NDA." Doc. #2 at ¶ 204. These allegations fail for numerous reasons.

First, the complaint wholly fails to plead when these documents were published or how Young herself relied on them. *See Cooper v. Samsung Elec. Am., Inc.*, No. 07-3853, 2008 WL 4513924, at *8 (D.N.J. Sep. 30, 2008) ("Cooper asserts that he relied on unspecified marketing and advertising materials related to the ... television he bought .... He does not, however, supply any details with respect to the marketing or advertising materials in question, characterizing instead their presumed effect upon a reasonable consumer. While such pleading may be consistent with claims under Rule 8(a), it fails to provide the particularity required by Rule 9(b)."") (internal quotation marks and citation omitted); *Asad v. Hartford Life Ins. Co.*, 116 F.Supp.2d 960, 963 (N.D. Ill. 2000) ("The complaint generically refers to 'policy illustration,' 'marketing materials,' and 'sales presentations' but never identifies which particular items form the basis of Hartford's alleged fraud.").

More importantly, Young makes no effort to identify specific documents or to link specific misrepresentations (or omissions) to such documents. Accordingly, this Court concludes that Young has failed to plead her fraud claims with particularity. *See House v. Bristol-Myers Squibb Co.*, 2017 WL 55876, at *9 (W.D. Ky. Jan 4, 2017) ("She alleges that Defendants committed fraud in unspecified labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, without

identifying or referencing a single particular document or statement.... [T]he Complaint's vague allegations simply do not suffice under Rule 9(b) because they discuss the alleged practices only at a high level of generality.") (internal quotation marks omitted).

V
Leave to Amend

In response to the motion to dismiss, Young asks for an opportunity to conduct discovery or for leave to amend her complaint. Doc. #17 at 21. However, under this Court's Local Rules, "[a] response to a motion may not include a counter-motion in the same document." L.U. Civ. R. 7(b)(3)(C). Nevertheless, "a plaintiff's failure to meet the specific pleading requirements should not automatically or inflexibl[y] result in dismissal of the complaint with prejudice to re-filing." 199 F.3d 239, 247 n.6 (5th Cir. 2000). Thus, "[a]lthough a court may dismiss [a] claim, it should not do so without granting leave to amend, unless the defect is simply incurable or the plaintiff has failed to plead with particularity after being afforded repeated opportunities to do so." *Id.* Upon consideration, the Court concludes that Young should be given an opportunity to correct the pleading deficiencies identified by this order. Accordingly, the dismissal of Young's claims will be without prejudice to filing an amended complaint.

VI
Conclusion

For the reasons explained above, the Removing Defendants' motion to dismiss [7], which was joined by the Non-Removing Defendants [20], is **GRANTED in Part and DENIED in Part** such that:

1. Young's common law claims for strict liability, negligence, breach of implied warranty, negligent misrepresentation, and fraud are dismissed.
2. Young's design defect claim is dismissed for failure to plead a feasible design

alternative.

3. Young's failure to warn claim based on Young's ketoacidosis is dismissed.

4. Young's manufacturing defect claim is dismissed.

5. Young's breach of express warranty claim is dismissed.

6. To the extent dismissal was sought under Rule 9(b), Young's claims for fraud, negligent misrepresentation, and violation of the Consumer Protection Act are dismissed.

7. The motion to dismiss is denied in all other respects on all other grounds.

8. Such dismissals described above shall be without prejudice to Young filing an amended complaint within twenty-one (21) days of this order.

SO ORDERED, this 22nd day of February, 2017.

/s/ Debra M. Brown
UNITED STATES DISTRICT JUDGE